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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR NOTICE INTERIM FINAL RULES"

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TR 11

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P R O C E E D I N G S

MS. AYLING: When we have questions, you have to come up to the mike.

MR: : As the agent for a foreign manufacturer, are there any legal ramifications to being that?

MR. EVANS: That's question, probably for--

MS. AYLING: Are there legal ramifications for a U.S. agent of a foreign manufacturer?

Like I said, both the statue and the regulation really focus on the U.S. agent as a communication. So, there have been questions about when would the U.S. agent be held liable. The U.S. agent would only be held liable if they intentionally provide false information as part of a registration or something else.

But, no, there were no specific duties or responsibilities. The only requirement is that they reside or maintain a place of business in the U.S., and that they are available in the U.s. as a contact.

MR. : So if I want to no longer be an agent for a foreign company, can I remove my name from that?

MS. AYLING: Right--in your packet--gee, I'm glad you brought that up--is Edition 3 of the questions and answers for registration. And I think they deal with that. There's a process that you need to come to us and tell us that you no longer want to be a U.S. agent for the firm, and what the registration number is, and then we somehow work that out.

I think it came up early when people were becoming U.S. agents without knowing it. And many of them wished to be removed. So we found a way of doing it.

MR: : Thanks.

MS. AYLING: Also, for any questions that you may have, I wanted to point out to you that as part of your packet, you have in red, kind of a lay version of the registration, and what the requirements of registration are. you have--and this is also on our website--you have questions and

answers, the 3rd Edition, for registration, that goes through the registration process, and deals with some of the questions we've got from the Help Desk and into referrals. We have an e-mail activity where we can get questions, and when they're generic questions, we try to answer them in this document. That's also on the website.

And then also, in your packet and on our website is a compliance policy guidance that deals--it's guidance for FDA staff, and it's also information for industry and public. It tells how we plan to enforce registration. And it--primarily for registration--it discusses that for the initial period we're going to use education a enforcement. We're going to make sure that people know that they're supposed to register; help them get through the process; answer their questions. As part of our routine inspection activities, we're going to check to see if firms that should be registered are.

And then after that period of time, it's going to be a kind of a case-by-case type of

enforcement. But this pretty much describes what it is. It starts out with an untitled letter to the firm, saying, hey, you know, you really should be registered. That's kind of an educational thing.

But if a firm fails to register and we believe it should be registered, then the next thing that would follow could be a warning letter. Now, a warning letter is titled "Warning Letter," and it comes directly to the firm. The other thing you should know about the warning letters is that they're available through Freedom of Information, and they're also posted--usually posted on the FDA website. So that if a firm fails to register, and we've been in this discourse with them, that will be public information.

The agency, by statue, cannot disclose registration or registration numbers. We're required to maintain a list for Congress, but we're not allowed to disclose that list, saying "ABC company has this registration number." However, our discourse on enforcement--if a firm is not

registered and should be, those warning letters are releasible through the Freedom of Information and are public.

Anything to add?

MR. : Yes. When you first register, you get a confirmation of registration, which shows what you've registered electronically, and you can print that out. When you modify your registration, is there plans to also have that sent out so that we get a confirmation that it was modified, so we can see--okay, I did my initial registration. A couple months later I had a change. I can print that out, circle what the changes are for future reference and ease for noticing those changes.

i have made changes and I haven't ben able to get that electronically. I just print it out before submitting so that I can have that. And I was just wondering if there's plans to have a confirmation after changing?

MR. MARINELLI: No there are no plans at the moment to send any additional notifications

regarding the registration. The initial one is simply to make sure that, indeed, this facility, or the person in charge of that facility, is aware that it's been registered. But there are no plans to send further notices, if there are updates.

There are some updates that--for example, if someone changes the PIN, then the facility will get notified of that. Or if the facility is cancelled--someone cancels it--the facility is notified of that.

But if you change an address, for example, we don't have plans to send a notification.

MS. FRY: However, the comment period is going to be opening again this month. And if you would find that to be really, really useful that would be a great comment to submit to the docket.

MR. : A question I have--can you go back into the system and see your changes? I mean, the changes would be recorded when you go back in?

MR. MARINELLI: Well, what you will see is the updated information.

MR. : Right.

MR. MARINELLI: Right. Right.

MR. : So you would be able to go back in and see your--

MR. MARINELLI: Right. Yes you can--at any time, you can go in and see what the current information is for that registration.

MR: : We are already registered, but we have a lot of audits and other third-party audits, and they're asking us if we have our suppliers registered.

And what is our obligation regarding our incoming ingredients, and their registrations--and, going even beyond that--their suppliers? And what obligation do we have, as a facility, to make sure that those suppliers register?

MS. AYLING: You don't have any obligation under the registration rule--or, actually, any other act or rule that I can think of, as an actual obligation of doing that. It certainly makes sense. It has gotten into a lot of questions about disclosing registration numbers, because we can't--

because FDA can't--the questions have come up, you know, "Should I disclose my registration number?"

And we discourage you from putting it on a label or forms or anything like that; don't really discourage you giving, you know, proof of registration. The printable form of confirmation would certainly be useable--except that it has both the registration number on it and the PIN number. And we certainly wouldn't recommend you give someone else your PIN. You don't need to give them registration number.

But there's kind of a challenge right now, of what kind of confirmation can you give, or can you ask for, that makes you feel comfortable that they are registered. But the responsibility for registering lies with the facility itself.

MR. : Just one other question. On the FDA website, there is guidance, or there is suggestion about plan security, employee background checks, screening employees--a variety of different things.

Is that--because it's on there, I wonder,

well is that going to be part of future regulation that's upcoming? Is that being discussed?

What's the intent of having that on there?

MS. FRY: The intent of that guidance--and it's "Food Security Preventive Measures Guidance," and there's four of them out there now. One is four manufacturers, processors, packers, holders and transporters. One's for importers and filers. One's for retail and food service establishments. And one's for cosmetics.

The purpose of those was one of our initial responses to September 11, is to put some guidance out there for what these different entities should do--you know, a checklist, kind of ideas. We never have intended for it to become a rule. I don't think, on our own volition that we'll make it rule. I hope we not--at least, from what I know.

And the only time I could think that it would get pushed to that is if we had some sort of statute from Congress telling us it has to be; or, if we have some God awful event, where industry

itself wasn't doing that and, as a result, there was a push to make it a rule.

My experience with the guidance has been that most industry either was doing it on their own, or was using what we had provided as a basis. There's a lot of, I know, exporters in Eastern Europe told us that immediately, their clients in the U.S. were requiring certain things. So it's kind of been kind of a self-regulated type of thing.

So, I don't see that going as regulation, but I see it--I was personally involved with this, so I just think it's great guidance--you know? And a lot of industry has done their own, as well.

MS. : I have two questions. One--I'm a broker here in Salt Lake, and as a filer, are we required to be registered with FDA?

MS. FRY: Now, registration involves: a facility--so, first, you have to be a facility, and you have to manufacture, process, pack or hold food.

MS. : Okay.

MS. FRY: So the question--we've gotten questions before--filers or importers. There are importers that don't ever have to register because they don't ever have possession of the food, or they don't do anything to it. If you're an importer that also has a warehouse where you hold the food, then you have to register as a holder of food.

MS. : Okay.

MS. FRY: So, for the most part, I can't think of many occasions when a broker would be required to register, unless you have a holding facility.

MS. : Okay. And then the second question: I have an importer that imports two different types of products from the U.K., one being barley seed to grow a crop. Would they be required for the FDA registration and prior notice for that? And then the second is, they import the barley seed to then make beer. So, obviously that would--yes. I understand that.

MS. FRY: Yes, I think in both--in the

preambles for both rules--both registration and prior notice. And then I think we've also discussed it in the Qs&As.

You get into these products that could be--or might not be--and a seed is a really good one. And what we've put in both of the preambles is that if anybody in the whole chain--you know, the importer, the broker, the manufacturer--has reason to believe that it is or will become a food product--that means food for people or for animals--then, yes. It's covered.

But if--and I know when you're talking as a broker you're talking about harmonized codes and the codes are "seeds used for sowing," but there isn't a separate code for seeds used for sprouting. So what we've done is we've marked those that can go either way, and just basically rely on the "if you have reason to believe that they're going to be used for a food product," then, yes, they have to register--if they're not a farm.

MS. : Right. Because that's the--but they are a farm. So--

MS. FRY: Yeah, if they're a farm--

MS. : --then they wouldn't--

MS. FRY: --registration--

MS. : Okay, because that was my second thing on that same thing is: on the FDA, when you're doing the FDA transmission, per se--

MS. FRY: Mm-hmm.

MS. : --it gives it an "03" code, which is "it could require," however it's a non-FDA required item. So then I just said, "Okay, well if it's a non-FDA required item, we really shouldn't have to have a prior notice.

MS. FRY: Right.

MS. : Is that reasonable?

MS. FRY: Yes, it's reasonable, and I don't know how applicable it is at this time, because what we intended is if it's got that kind of flag, that you could disclaim it for prior notice, but you could still--

MS. : You could prior notice it.

MS. FRY: --give us, you know, regular information if--you know, because we have all these

categories now.

MS. : Right. Right. Right. So--

MS. FRY: So, as far as I know, that hasn't necessarily been activated yet, but it will.

MS. : Okay.

MS. FRY: So you'll be able to do that.

MS. : Thank you.

[Pause.]

MR. : My question relates to transport vehicles. If a transport vehicle is used in the normal business, but it's left at a retail location for a period of time--several weeks--is it still considered exempt as a transport vehicle, or is it a separate facility?

MS. FRY: It becomes a separate facility. What we meant by "in the normal course of transportation," is when a transport vehicle may sit overnight someplace, or if it's in a container yard type of thing and it's sitting there because it's waiting for the next truck to come along and take it, or it's waiting to be put on a rail car.

but when you use transport vehicle as a warehouse, then it becomes a warehouse.

MR. : Okay. So, how do you handle the registration on that, when it may not be at the same location--

MS. FRY: It's like one of those mobile wine bottlers. There's a way, in the registration, where you--I think--you say it's a mobile facility. But then you can give the location where it's consolidated, or--you know, you may have--I know these wine bottlers may have like three or four trucks that go around--the trucks are all mobile, but there is a location where there's an address where it's all kind of consolidated.

MR. : Okay. Thank you.

MS. FRY: Any other questions?

Kim, do you have anything you want to add from the animal side?

MR. YOUNG: I just wondered how many people deal with animal products?

MS. FRY: That are here today?

MR. YOUNG: Okay--so--is that in the grain

or the live animal? Grain aspect.

The--I'll just go over some of the--well, the major question in regards to grain facilities is "When do I--"--you know, "I have various silos. Do I have to register each silo? Or how does that work?" And with that is: with the address. I mean, if you're talking silos on one farm, same address, you have to do the various silos. If you have a different farm, with some other silos on it, then it's a different address, then you would have to register those silos separately.

I mean--that's one of the main questions or concerns that people have in regards to the grain.

[Pause.]

MR. : If I hand-carry QC samples here from China, I would need to do the prior notice. If I send it UPS, I would not have to? Or if I mail it, through international mail, I would have to--is that right?

MR. YOUNG: You'd have to submit prior notice in all three cases.

MR. : All three cases.

MR. YOUNG: Right.

MR. : I was confused on the definition of "international mail," I guess. Does that include UPS and FedEx?

MS. FRY: No.

MR. : But you still have to anyway.

MS. FRY: But those are not excluded.

MR. : It's not excluded.

MS. FRY: UPS is not excluded.

MR. : Okay.

[Pause.]

MS. : [Off mike.] I don't usually need a microphone, so--

MS. FRY: It's related to the tape recorded.

MS. : [Off mike.] [inaudible].

I don't believe a U.S. manufactured product coming back into the country is subject to product notice. Is that true?

MS. FRY: Say again?

MS. : U.S. manufactured product that comes back into this country does not appear to be subject to prior notice? The harmonized code does not queue up as a code "03" or "04."

MS. FRY: It is required.

MS. : It is required?

MS. FRY: Right.

MS. : Okay. Then Customs needs to fix their system, maybe--huh? If you use the Tariff 9801?

MS. FRY: Most of the 9801s are on FD-3. What you should do, if you get any soon, is let Customs know that it's not coming up as a "03." In the future, you'll have the ability to transmit prior notice regardless of the flag.

MS. : Okay.

MS. FRY: All right? And that change should be in place, I would say, before the end of the next month--at least.

MR. YOUNG: In your folders, you have a compliance policy guide which explains how we are handling the prior notice information that's coming

in, in which we have a period of time for people to learn what the regulations consist of. And that just because, you know, on the date of implementation, we'd not just stop everything coming in. So that explains the step-by-step process for allowing a product coming in as you're learning more and more about the prior notice regulation.

Also, along with the registration booklet that Mary had mentioned earlier, there is a "What you Need to Know About Prior Notice of Imported Food Products" in your packet.

MS. FRY: You know, along the same note, Mary showed you Qs and As for registration. There are also Qs and As for prior notice, although they're not included. You can get those from the website.

[Session concluded.]

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